Applicant respectfully disagrees with the Examiner's conclusion, claim 9 has been cancelled.

Claim 10 was rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. Claim 10 has been cancelled.

Claims 1-8 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 3,818,911 to <u>Fournier</u>. Applicant respectfully traverses this rejection.

Claim 1, as amended, is directed to a substance delivery device including, *inter alia*, a "substance dispenser including a plurality of fingers radiating from a central aperture" and "means for releasably fixing the substance dispenser to the supporting structure so that the central aperture slides over a portion of the support structure."

Fournier does not anticipate a substance delivery device including "means for releasably fixing the substance dispenser to the supporting structure so that the central aperture slides over a portion of the support structure."

Specifically, <u>Fournier</u> discloses a grippable support member 10, a narrow shaft 12, and a polymeric foam material 17 affixed to the narrow shaft 12. <u>Fournier</u> also states "[t]he base member may be so constructed that it can be detached an reused as a holder for fully disposable applicator tips (separately supplied) which comprise the cured polymeric foam layer and its supporting structure." See col. 4, lines 57-62. This arrangement teaches away from the subject invention. <u>Fournier</u> teaches that the grippable support member 10 is detachable from an assembly which includes the narrow shaft 17 and polymeric foam material 17. It is the grippable support member 10 and not the polymeric foam material 17 that is detachable from the narrow shaft 12.

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Furthermore, the disposable applicator tip is a single item and does not have a central aperture. As recited in claim 1, the substance dispenser includes a central aperture which allows the substance dispenser to be releasably fixed to the supporting structure. This allows the substance dispenser to be readily changed and also allows customization of the drug delivery and dosage to suit the individual situation.

Finally, the subject invention is designed to be retained within the body cavity for the sustained release of drugs over a period of time. <u>Fournier</u>, in contrast, is designed to be used as an applicator swab. The applicator swab is used to apply a single dose of a medication composition to an internal body surface. See col. I, lines 44-47. For these reasons, Fournier does not anticipate claim 1 and the rejection should be withdrawn.

Claims 2-8 depend from claim 1 and are allowable for at least the same reasons that claim 1 is allowable, as well as for their independently recited subject matter.

In view of the foregoing amendments and remarks, Applicant respectfully requests the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: October 5, 2001

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APPENDIX TO AMENDMENT

Version with Markings to Show Changes Made

Amendments to the Claims

1. (Amended) A substance delivery device <u>comprising:</u>[, including a substance dispenser fixed to a supporting structure by a releasable fixing means wherein the releasable fixing means includes a substance dispenser having a central aperture allowing the substance dispenser to slide over a corresponding section of the supporting structure and be readily removed from same, characterized in that the surface area of the substance dispenser is independent of the supporting structure and the substance dispenser is in the form of fingers extending from the support structure]

a supporting structure;

a substance dispenser independent of the supporting structure, the substance dispenser including a plurality of fingers radiating from a central aperture; and

means for releasably fixing the substance dispenser to the supporting
structure so that the central aperture slides over a portion of the support structure, and
so that the plurality of fingers extend away from the supporting structure.

- 4. (Amended) A substance delivery device as claimed <u>in</u> any one of claims 1 to 3 wherein the fingers are coated or impregnated with the substance to be dispensed.
- 5. (Amended) A [drug] <u>substance</u> delivery device as claimed in any one of claims 1 to [4] <u>3</u> wherein the substance dispenser is made from polydimethylsiloxane.

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- 6. (Amended) A substance delivery device as claimed in any one of claims 1 to [5] 3 wherein the substance dispenser is highly flexible.
- 7. (Amended) A substance delivery device as claimed in any one of claims 1 to [6] 3 in the form of [a] an intravaginal release device.
- 8. (Amended) A substance delivery device as claimed in any one of claims 1 to [7] 3 for use with cows.

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